

Appl. No. 10/032,962
Amdt dated September 28, 2005
Reply to Office Action of June 28, 2005

REMARKS

Applicant has carefully reviewed the Office Action mailed June 28, 2005. Currently claims 1-5 and 7-22 are pending in the application, and claims 7, 9, 10, 15 and 17-22 have been withdrawn from consideration. Claims 1-5, 8, 11-14 and 16 have been rejected. Claim 11 has been amended. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections—35 U.S.C. § 112

Claims 11-14 and 16 were rejected under 35 U.S.C. § 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner states, “[C]laim 11 is confusing and inaccurate since it appears to incorrectly indicate that the material volume per unit length of the balloon waist is altered at thermal reformation.” Claim 11 has been amended to more clearly indicate that material volume per unit length is altered prior to thermal reformation. Claims 12-14 and 16 depend from claim 11 and contain additional elements. Applicant therefore respectfully submits that claims 11-14 and 16 are in compliance with 35 U.S.C. § 112, ¶ 2 and requests withdrawal of this rejection.

Claim Rejections—35 U.S.C. §§ 102 & 103

Claims 1-5, 8, 11-14 and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by Shoup et al. (U.S. Patent No. 5,591,129) or in the alternative under 35 U.S.C. § 103(a) as obvious over Shoup et al. Applicant respectfully traverses the rejection.

Shoup et al. disclose a balloon angioplasty catheter having a balloon head assembly at the distal end that includes an inflatable balloon envelope and a perfusion lumen extending therethrough. Shoup et al. do not disclose, however, a balloon waist including a plurality of voids.

Balloons in intravascular applications such as angioplasty and stent delivery are known to generally have five main sections: the balloon body, proximal and distal cones, and proximal and distal waists. The balloon body is the central section that inflates to a desired therapeutic profile. The proximal and distal cones are sections that taper down from the central section to the balloon

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waists. The proximal and distal waists seal the balloon to underlying components such as the tubular members making up a catheter shaft.

The descriptions of the balloons in Shoup et al. are consistent with this use of the terminology. "Balloon assembly 10 includes a balloon envelope 16 which may be formed of a polyethylene/EVA blend, for example. A perfusion lumen 17 extends through the interior of the balloon envelope 16 from a proximal balloon waist 18 to a distal balloon waist 19." See column 4, line 64 through column 5, line 1. Notably, Shoup et al. discuss the areas where orifices 26 and 27 occur and the void above tapered portion 30 as being other than the balloon waists. "A balloon assembly tip 25 extends distally from the balloon envelope and the distal end of perfusion lumen 17 and defines a discharge lumen therein. The projection tip 25 is provided with a plurality of discharge orifices 26 and 27." Column 5, lines 33-36. "Balloon assembly 10 further includes a generally cylindrical proximal extension from waist 18 indicated generally at 30." Columns 13-15. In other words, Shoup et al. describes balloon assembly tip 25, where orifices 26 and 27 are located, as distal to distal balloon waist 19 and projection 30 as proximal to proximal balloon waist 18.

Even though the balloon assembly tip is unitary with the distal balloon waist and projection 30 is unitary with the proximal balloon waist, they are distinct components. The balloon waists are part of the balloon envelope and function to seal the balloon cavity. The balloon assembly tip and projection 30 provide distinct functions relating to perfusion. Just as for a knife, one could not say that the tang is the blade even though they are made from the same piece of metal, one cannot say that the balloon assembly tip is part of the distal balloon waist merely because they may be part of the same piece of material.

With this in mind, it becomes easy to see that all the features of the claimed invention are not disclosed by Shoup et al. Claim 1 recites "the balloon waist including a plurality of voids." As discussed above, none of the balloon waists disclosed by Shoup et al. have any voids; on the contrary the balloon waists of Shoup et al. are typical balloon waists with no voids at all through the walls thereof. As Shoup et al. do not disclose all the features of the invention of claim 1, applicant submits that claim 1 is not anticipated by Shoup et al. Further, Shoup et al. disclose no suggestion or motivation to create voids in a balloon waist. Applicant therefore respectfully submits that claim 1 is non-obvious over Shoup et al. Applicant submits that claim 11, which

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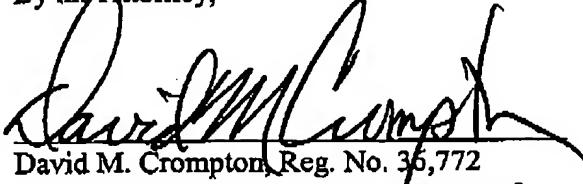
recites "means for altering the material volume per unit length over a substantial portion of the balloon waist prior to thermal reformation," is allowable for similar reasons. As each of claims 2-5, 8, 12-14 and 16 depend directly or indirectly from one of claims 1 and 11 and contain additional elements, Applicant submits that these claims are in condition for allowance as well.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,



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